FEB 2 4 2005

K043410

Section XII: 510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990

510(k) Summary

NAME OF FIRM: I.T.S. Implantat-Technologie-Systeme GmbH.
Autal 28.
Lassnitzhoehe A – 8301
AUSTRIA

510(k) FIRM CONTACT: Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372

TRADE NAME: Epiphysis Screw

COMMON NAME: Cannulated Bone Screw

CLASSIFICATION: Smooth or threaded metallic bone fixation fastener

(see 21 CRF, Sec. 888.3040).

DEVICE PRODUCT CODE: HWC

SUBSTANTIALLY EQUIVALENT DEVICES:
Synthes 6.5mm Cannulated Screw **(K021932)**
Howmedica Osteonics ASNIS III Cannulated Screw **(K000080)**
Orthomet/Wright Medical Cannulated Screw **(K862157)**
Ace/Depuy Cannulated Self Tapping Cancellous Bone Screw **(K903810)**
Zimmer MAGNA-Fx Cannulated Screw Fixation system
Richards/Smith Nephew Universal Cannulated Screw
DePuyAce ACE SCFE Screw

DEVICE DESCRIPTION: The I.T.S. Epiphysis Screw is a self-tapping and self-drilling screw with a cancellous thread that can be guided into a position via a guidewire pin. Screws are available partially threaded in lengths from 50mm to 120mm in 5mm increments. A full complement of instrumentation is available to assist in placement. The screws are manufactured from 6-4 ELI Titanium alloy with a Tiodize, Type II surface.

INTENDED USE: The I.T.S. Epiphysis Screw is used to stabilize a slipped capital femoral epiphysis and fracture fixation in the pelvis of large bones and large bone fragments. The system is not intended for spinal use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 4 2005

I.T.S. Implant-Technologie-SystemeGMBH
Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th Street
Prior Lake, Minnesota 55372

Re: K043410
Trade/Device Name: Epiphysis Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: December 10, 2004
Received: December 10, 2004

Dear Mr. Al Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

I.T.S.

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I.T.S. Implant-Technology-Systems GmbH
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Indications for Use

510(k) NUMBER: K043410

DEVICE NAME: EPIPHYSIS SCREW

INDICATIONS FOR USE:

The I.T.S. Epiphysis Screw is a titanium implant fracture fixation screw system for a slipped femoral capital epiphysis and alternative cancellous bone screw fixation where accurate screw placement is required such as in the pelvis, ankle, knee, etc..

Indications for Use include fracture fixation of large bone fragments, such as femoral neck fractures; slipped capital femoral epiphysis; tibial plateau fractures; pediatric femoral neck fractures; intercondylar femur fractures; and subtalar arthrodeses.

The system is not intended for spinal use.

Prescription Use X AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801.Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

K043410

510(k) Number

Section XI